Docket No.: 15651-002001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Andrew Schydlowsky	Examiner: Richard C. Weisberger
Serial No.: 10/697,767	Group Art Unit: 3693
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For: CUSTOM FOOD	

Mail Stop Appeal Brief
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

BRIEF ON APPEAL

(1) Real Party in Interest

The real party in interest is Kala International, Ltd.

(2) Related Appeals and Interferences

None.

(3) Status of Claims

Claims 26-29, 31, 33, 34, and 46-49 are pending and stand finally rejected.

Claims 1-25 and 44 have been cancelled in a Response dated August 31, 2005.

Claims 35-43 have been cancelled in a Response dated March 6, 2006.

Claims 30, 32, and 45 have been cancelled in Response dated November 14, 2006.

Applicant appeals the rejections of claims 26-29, 31, 33, 34, and 46-49.

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(4) Status of Amendments

All claim amendments were entered prior to the final Office Action, and no claim amendments are pending.

(5) Summary of Claimed Subject Matter

One independent claim is involved in this appeal, claims 26.

The invention of independent claim 26 is a kit for making a nutritional supplement. The kit comprises a dietary supplement product and at least one additive, wherein the additive is packaged separately from the dietary supplement product. The dietary supplement product is a powder comprising one or more of a protein, peptide, amino acid, carbohydrate, electrolyte, herb, or combination thereof. See, e.g., specification at page 2, lines 20-22; page 4, line 14; page 4, line 19 to page 5, line 16; page 8, lines 10-28; and original claims 26, 27, 30, and 32.

(6) Grounds of Rejection to be Reviewed on Appeal

Rejection 1: Claims 26-29, 31, 33, 34, and 46-49 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite.

Rejection 2: Claims 26-29, 31, 33, 34, and 46-49 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Morrissette *et al.* U.S. Publication No. 2002/0150658.

(7) Argument

Rejection 1: Whether claims 26-29, 31, 33, 34, and 46-49 are indefinite.

A. Grouping of Claims for Rejection 1

Claims 26-29, 31, 33, 34, and 46-49 stand or fall together.

B. Arguments for Reversal of Examiner's Rejection 1

Claims 26-29, 31, 33, 34, and 46-49 stand rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. In particular, the Examiner asserted that the term "powder" is indefinite in scope. Office Action of October 18, 2007 at page 2.

Applicant respectfully disagrees. The standard for satisfaction of 35 U.S.C. § 112, second paragraph, is whether "one skilled in the art would understand what is claimed." *See Amgen, Inc. v. Chugai Pharmaceutical Co.*, Ltd. 927 F.2d 1200 (Fed. Cir. 1991). In addition, the Federal Circuit has stated that claims need only "reasonably apprise those skilled in the art" as to their scope and be "as precise as the subject matter permits." *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367 (Fed. Cir. 1986). Moreover, MPEP § 2111 states that claims must be given their broadest reasonable interpretation *consistent* with the specification; this interpretation must be *consistent* with the interpretation that those skilled in the art would reach. Importantly, the section goes on to state that the "plain meaning" is the ordinary and customary meaning given to the term by those of ordinary skill in the art, and that it is the use of the words in the *context of the written description* and *customarily by those skilled in the relevant art* that accurately reflects the "ordinary" and "customary" meaning of the terms (emphasis added). One having ordinary skill in the relevant art, or nutritional supplement products here, would understand the scope of the term "powder" and would interpret the term "powder" consistently with the generally accepted definition of the term to mean a substance consisting of ground or finely divided or dispersed solid particles (see Evidence Exhibits A-C). There is simply nothing in the specification to indicate otherwise, nor is there a requirement, given the context of nutritional supplements, for Applicant to have defined the term "powder" with some sort of exacting size distribution. The Federal Circuit has stated that a "patentee need not define his invention with mathematical precision in order to comply with the definiteness requirement." *See In re Marosi*, 710 F.2d 799, (Fed. Cir. 1983).

Furthermore, Applicant notes that the term "powder" is indicated in the specification to be one example of a "form" of a base (the dietary supplement here); the other possible forms include solid, semi-solid, and liquid. Specification at page 4, lines 17-18. To indicate that the base can be in "powder" form as one form in addition to solid or liquid forms is consistent with a definition of powder which indicates that powder particles behave intermediately between that of a solid and a liquid (see Evidence Exhibit C entry www.unistates.com/rt/explained/glossary/rmtglossarypq.html). Given all of the above, Applicant asserts that the term "powder" is not indefinite, as one having ordinary skill in the art would understand the scope of the term in the context of nutritional supplements and within the context

of the term as used in the specification. The Examiner has thus applied an improper standard for definiteness given the specification, context, and case law referenced above. Accordingly, the Board is requested to reverse the rejection of claims 26-29, 31, 33, 34, and 46-49 under 35 U.S.C. § 112, second paragraph.

Rejection 2: Whether claims 26-29, 31, 33, 34, and 46-49 are anticipated by Morrissette *et al.* U.S. Publication No. 2002/0150658

A. Grouping of Claims for Rejection 2

Claims 26-29, 31, 33, 34, and 46-49 stand or fall together.

B. Arguments for Reversal of Examiner's Rejection 2

Claims 26-29, 31, 33, 34, and 46-49 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Morrissette *et al.* U.S. Publication No. 2002/0150658 (hereinafter, "Morrissette"). Evidence Exhibit D. In particular, the Examiner alleged that Morrissette teaches a kit comprising a dietary supplement powder product, because the Examiner stated that the term powder reads on "ready-to-eat cereal." Office Action of October 18, 2007 at page 2.

Applicant respectfully disagrees. A claim is anticipated under § 102(b) only if each and every limitation is disclosed in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 639 (Fed. Cir. 1989) and MPEP § 2131. Present claim 26 recites, among other things, a kit for making a nutritional supplement comprising a dietary supplement product, where the dietary supplement product is a powder. For the prior reasons of records as well as those discussed herein, Applicant asserts that neither of the terms "dietary supplement" nor "powder" read on any of the food components disclosed in Morrissette. Morrissette discloses that food components such as ready-to-eat cereals (e.g., whole wheat flakes) or the gasified candy known as "poprocks" can be included in his food package system. Morrissette paragraph [0010]. It is simply unreasonable to assert that cereal flakes and poprocks anticipate the claim terms "powder" and "dietary supplement."

Applicant respectfully assert that the term "dietary supplement" is a term of art having a defined meaning. One having ordinary skill in the art would have understood, from a time well before the date of the present filing, that the term "dietary supplement" means products that are

intended to supplement the diet and that are not represented for use as a conventional food or staple of the diet. Indeed, as previously stated in a Response dated March 6, 2006, in the United States, a dietary supplement is defined under the Dietary Supplement Health and Education Act of 1994 as a product that meets each of the following criteria (see Evidence Exhibit E):

1. It is intended to supplement the diet and bears or contains one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical (excluding tobacco), an amino acid, a dietary substance for use by man to supplement the diet by increasing the total daily intake (e.g., enzymes or tissues from organs or glands), a concentrate, such as a meal replacement or energy bar, or a metabolite, constituent, or extract.
2. It is intended for ingestion in pill, capsule, tablet, or liquid form.
3. It is not represented for use as a conventional food or as the sole item of a meal or diet.
4. It is labeled as a "dietary supplement".

Thus, as can be seen from the above, the term "dietary supplement" has had a defined meaning since 1994 to one having ordinary skill in the art. In further support, Applicant refers to page 4, line 7 of the present specification, where dietary supplement bases "such as a muscle building or protein powder" are described. Such dietary supplement bases are consistent with the above definition and are clearly not conventional foods. Applicant asserts that one having ordinary skill in the art would therefore understand ready-to-eat-cereals to be a conventional food and not a "dietary supplement." Moreover, the guidelines described above would require a ready-to-eat cereal to be labeled as a "dietary supplement" if it were considered such by those having ordinary skill in the art, which it is not. In addition, in listing examples of base items that can be used in various embodiments of the present invention, dietary supplements and other conventional food items (e.g., cereals) are listed separately, clearly indicating that Applicants intended these items to be considered as independent species.

As indicated above, a "powder" is generally accepted to be a *ground or finely divided* particulate composition. Neither "poprocks" nor a ready-to-eat cereal, such as the whole-wheat flakes of Morrissette, are "ground" or "finely" divided particles, let alone "dietary supplements" in such a form.

In an Office Action dated October 18, 2007, in responding to Applicant's previous response, the Examiner stated that "[a] critical read of the prior art includes, for example, fluid

batters which is a powder in combination with a liquid. Moreover, the Morrisssette teaches that this fluid batter can be dry (col 2., ll. 16-17)." Office Action of October 18, 2007 at page 3.

Applicant disagrees with the Examiner's interpretation of the prior art. With respect to the fluid batter, as pointed to by the Examiner, Morrissette states:

> In still another variations [*sic*] the *wet* material component can comprise a *fluid batter* such as a farinaceous batter for chemically leavened baked goods (e.g., layer cakes, muffins, quick breads, brownies or other dessert baked goods) or pan goods (e.g., pancakes) such as including an acidulant or at least one baking acid and *the dry component can be a chemical leavening system or component thereof such as baking powder or soda* (sodium bicarbonate).
> Morrissette column 2, lines 2-9; emphasis added.

Accordingly, Applicant asserts that Morrissette is disclosing the separation of a fluid batter (e.g., an acidulant or baking acid containing component) from a dry component (e.g., a chemical leavening system). A fluid batter is not a "dietary supplement." Moreover, even if one were to interpret a fluid batter to be a "dietary supplement," at no point does Morrissette state that the fluid batter could be in powder or dry form as asserted by the Examiner. In fact, Morrissette defined the fluid batter as the *wet* component of the invention. The Examiner alleges that the fluid batter can be dry by citing the following from Morrissette (Office Action of October 18, 2007 at page 3):

> In still other variations, each food component can be dry but of differing water activities or moisture content. For example, one food component can be a dry ready-to-eat cereal with a water activity below about 0.3 (A_w less than 0.3), e.g., whole wheat flakes, while the second food ingredient has a higher water activity, e.g., raisins having a $A_w \approx 0.4$ (col. 2, lines 15-21).

Applicant asserts that the Examiner has clearly taken the above passage out of context.

The Examiner has continually applied an unreasonable definition that is not consistent with Applicant's specification or the plain meaning of the term dietary supplement as would be understood by one of ordinary skill in the art to which this disclosure belongs. As discussed above, MPEP § 2111 states that claims must be given their broadest reasonable interpretation *consistent* with the specification; this interpretation must be *consistent* with the interpretation that those skilled in the art would reach. Importantly, the section goes on to state that the "plain meaning" is the ordinary and customary meaning given to the term by those of ordinary skill in the art, and that it is the use of the words in the *context of the written description* and *customarily by those skilled in the relevant art* that accurately reflects the "ordinary" and "customary"

meaning of the terms (emphasis added). Applicant asserts that based on the specification and the ordinary and customary meaning of the term, one of ordinary skill in the art of nutritional supplements would not consider a "ready-to-eat cereal", "poprocks", or a "fluid batter" to be dietary supplements.

In view of the above, Applicant asserts that Morrissette does not disclose each and every limitation in the claims and therefore does not anticipate them. Accordingly, Applicant respectfully requests that the Board withdraw the rejection of claim 26-29, 31, 33, 34, and 46-49 under 35 U.S.C. § 102(b).

Applicant asserts that the Examiner has applied an improper standard for definiteness. Applicant asserts that the term "powder" has a plain meaning (i.e., a substance consisting of ground or finely divided or dispersed solid particles) which would be understood by one of ordinary skill in the art based on the use of the term in the art and the context in which the term is used throughout the specification. With respect to the Examiner's § 102(b) rejection, Applicant asserts that Morrissette does not anticipate the pending claims. Specifically, the ready-to-eat cereal, "poprocks", and fluid batter of Morrissette are not "dietary supplements" in "powder" form as required by the instant claims. Accordingly, Applicant respectfully requests that the panel withdraw the rejections of claims 26-29, 31, 33, 34, and 46-49 under 35 U.S.C. § 112, second paragraph and 35 U.S.C. § 102(b).

Conclusion

Applicants respectfully request that the Board reverse the rejection of claims 26-29, 31, 33, 34, and 46-49 under 35 U.S.C. § 112, second paragraph and the rejection under 35 U.S.C. § 102(b) of claims 26-29, 31, 33, 34, and 46-49 over Morrissette.

Please charge the brief fee of $255 to Deposit Account No. 06-1050 Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: 8/18/09

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(8) Claims Appendix

26. A kit for making a nutritional supplement comprising:

a dietary supplement product, wherein the dietary supplement product is a powder comprising one or more of a protein, peptide, amino acid, carbohydrate, electrolyte, herb, or combination thereof; and

at least one additive, wherein the additive is packaged separately from the dietary supplement product.

27. The kit of claim 26, wherein the at least one additive when combined with the dietary supplement product, at a time after the manufacture of both the dietary supplement product and the additive, alters a characteristic of the dietary supplement product.

28. The kit of claim 26, wherein the additive is a flavorant.

29. The kit of claim 28, wherein the flavorant is selected from a group consisting of vanilla, chocolate, butterscotch, peanut butter, mocha, strawberry, banana, peach, orange, cherry, blueberry, raspberry, mango, apple, pineapple, grape, mint, caramel, cinnamon and combinations thereof.

31. The kit of claim 26, wherein the additive comprises a material selected from the group consisting of proteins, peptide, amino acids, carbohydrates, electrolytes, herbs, and combinations thereof.

33. The kit of claim 26, wherein the kit comprises a plurality of individually packaged additives.

34. The kit of claim 33, wherein the dietary supplement product is apportionable into single servings and the number of individually packaged additives is equal to at least the number of single servings of the dietary supplement product.

46. The kit of claim 26, wherein the dietary supplement product is contained in a first package and the additive package is held adjacent to the dietary supplement product package.

47. The kit of claim 26, wherein the dietary supplement product and the at least one additive package are combined into one package.

48. The kit of claim 26, wherein the dietary supplement product is contained in a package, the package comprising a holder adapted to hold the at least one additive package.

49. The kit of claim 48, wherein the holder is integral with the dietary supplement product package.

(9) Evidence Appendix

Appendix	Document	Date Entered
A	Definition of "powder" from Websters' Third New International Dictionary (1993), Merriam Webster, Inc., Springfield MA	Response filed August 8, 2007
B	Definition of "powder" from Answers.com	Response filed August 8, 2007
C	Compilation of definitions of "powder" from Google.com	Response filed August 8, 2007
D	Morrissette, et al. U.S. Publication No. 2002/0150658	Office Action of February 2, 2007
E	Dietary Supplement Health and Education Act of 1994	Response filed March 6, 2006

(10) Related Proceedings Appendix

None.